DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 27, 2015

Lightmed Corp.
Ms. Angel Hsieh
Regulatory Affairs Coordinator
No.1-1, Ln1,Pao-An St., Shulin Dist
New Taipei City, 23861 Taiwan, R.O.C.

Re: K142172
Trade/Device Name: Lightmed Truscan 577
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: January 27, 2015
Received: January 28, 2015

Dear Ms. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, MD
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142172

Device Name
LightMed TruScan 577 Laser System

Indications for Use *(Describe)*
The LightMed TruScan 577 Laser System is intended for use in the treatment of ocular pathology in the posterior segment; Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structure abnormalities of the retina and choroid including:

1. Proliferative and Severe and very severe nonproliferative diabetic retinopathy
2. Clinically Significant Macular edema
3. Choroidal neovascularization
4. Branch and central retinal vein occlusion
5. The treatment of choroidal neovascularization associated with wet age-related macular degeneration
6. Lattice degeneration
7. Retinal tears and detachments

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This is 510(K) summery in accordance with 21 CFR 807.92.

I. SUBMITTER

LightMed Corporation
No1-1, Ln1, Sec. 3 Pao-An St., Shulin Dist., New Taipei City 23861, Taiwan, R.O.C.
TEL: +886 2 2688 1726
FAX: +886 2 2676 4920
Establishment registration number: 3008156177
Contact person in Taiwan: Angel Hsieh, Regulatory Affairs Coordinator
Summary Preparation Date: February 25 2015

II. DEVICE

Trade name: LightMed TruScan 577 Laser System
The common name of the device: Laser Instrument, surgical, powered & Laser, ophthalmic
The classification name: 21 CFR 886.4390, Class II
Product code: HQF
Performance Standards: 21 CFR 1040.10 & 21 CFR 1040.11

III. PREDICATE DEVICE

PASCAL Streamline 577 (with Accessories), K111108
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

LightMed TruScan 577 is an integrated system consisting of Laser Console utilizing a 577nm Optically Pumped Semiconductor (OPSL; solid state) laser cavity, TruScan integrated Slit Lamp technology controlled via a LCD touch panel and wheel chair accessible ophthalmic instrument table.

The TruScan module which is integrated Slitlamp with safety filter as Laser Delivery System, employs a traditional single spot treatment laser, as well as a semi-automated pattern generation method employing short 577nm laser pulse durations of typically 10ms; range of spot size from 50µm to 400µm in a continuous adjustment.

The LightMed TruScan 577 Laser System is intended for use by ophthalmologist for treatment of ocular pathology.

The LightMed TruScan 577 Laser System is comprised of the following functional components:

- LCD touch panel
- Laser Console
- Ophthalmic Instrument table
- TruScan integrated CSO Slitlamp (K992836)

V. INDICATIONS FOR USE

The LightMed TruScan 577 Laser System is intended for use in the treatment of ocular pathology in the posterior segment; Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structure abnormalities of the retina and choroid including:

- Proliferative and Severe and very severe nonproliferative diabetic retinopathy
- Clinically Significant Macular edema
- Choroidal neovascularization
- Branch and central retinal vein occlusion
- The treatment of choroidal neovascularization associated with wet age-related macular degeneration
- Lattice degeneration
- Retinal tears and detachments

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

TruScan 577 is compared with predicate as STANDARD type of Pascal Streamline 577 only.

K number	K142172	K111108	Comparison of Same or Difference
Company name	LightMed Corporation	TOPCON Medical Laser Systems	
Device name	LightMed TruScan 577	PASCAL Streamline 577	
Indications for Use	● Proliferative and severe and very severe nonproliferative diabetic retinopathy ● Macular edema ● Clinically Significant Choroidal neovascularization ● Branch and central retinal vein occlusion ● The treatment of choroidal neovascularization associated with wet age-related macular degeneration ● Lattice degeneration ● Retinal tears and detachments	The PASCAL® Streamline 577 (with Accessories) is intended for use in the treatment of ocular pathology in the posterior segment; Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including: * proliferative and nonproliferative diabetic retinopathy *macular edema *choroidal neovascularization *branch and central retinal vein occlusion *the treatment of choroidal neovascularization associated with wet age-related macular degeneration * lattice degeneration *retinal tears and detachments	Similar

		* retinopathy of prematurity Intended for use in the treatment of ocular pathology in the anterior segment including: * iridotomy * trabeculoplasty	
Treatment Laser			
Wavelength	577nm	577nm	Same
Laser Type	OPSL-Optically Pumped Semiconductor Laser	OPSL-Optically Pumped Semiconductor Laser	Same
Power Output	50-2000mW	30-2000mW	Difference
Pulse Duration	10ms to 3s, continuous	5-1000ms	Difference
Pulsing System	Continuous	Continuous	Same
Integrated Slitlamp Multi Spot size	50(single spot only),100,200,300,400 μm selectable on Zoom assembly of Delivery unit	Slitlamp Microscope (integrated) 60,100,200,300,400 μm delivered to the focal plane of the slitlamp in air	Difference
Laser Safety Class	Class IV	Class IV	Same
Cooling method	Fan cooled and TEC's for Laser Diode and Crystal	TEC/ Air cooled	Same
Aiming Beam			
Wavelength	635nm red laser diode	635nm Direct Diode	Same
Power output	Maximum of 1.0mW	Adjustable to <1mW	Same
Laser Safety Class	Class II	Class II	Same
Other			
Interface	LCD Touch panel	LCD Touch panel	Same
General Electrical Input	100-230 Vac	100-240 Vac	Difference
Computer control	Yes	Yes	Same

Can user change computer program	No	No	Same

The Indications for Use statement for the LightMed TruScan 577 device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The performance data to account for the differences listed in the table are provided in Section VII of this summary below.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Bench Testing were completed including the Finished Product final assembly quality Inspection, System Adjustment, Calibration and Testing for Laser console and TruScan laser delivery unit on TruScan 577 Laser System.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the TruScan 577 device, consisting of the laser console and TruScan module integrated Slitlamp. The system complies with the IEC 60601-1, IEC 60601-2-22 and IEC 60825-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the TruScan 577 Laser System should perform as intended in the specified use conditions. The clinical evaluation data demonstrate that the TruScan 577 Laser System performs comparably to the predicate device that is currently marketed for the same intended use.